

Blood test shows promise in detecting abusive head trauma in infants

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Researchers at Children's Hospital of Pittsburgh of UPMC and University of Pittsburgh School of Medicine have developed and refined a blood test that could help clinicians identify infants who may have had

bleeding of the brain as a result of abusive head trauma, sometimes referred to as shaken baby syndrome. The science behind the test is described today in *JAMA Pediatrics*.

The serum-based [test](#), which needs to be validated in a larger population and receive regulatory approval before being used in clinical practice, would be the first of its kind to be used to detect acute intracranial hemorrhage, or bleeding of the [brain](#). Infants who test positive would then have further evaluation via brain imaging to determine the source of the bleeding.

"Abusive head trauma (AHT) is the leading cause of death from [traumatic brain injury](#) in [infants](#) and the leading cause of death from physical abuse in the United States," said senior author Rachel Berger, M.D., M.P.H., chief of the Child Advocacy Center at Children's Hospital and professor of pediatrics at the Pitt School of Medicine.

However, approximately 30 percent of AHT diagnoses are missed when caretakers provide inaccurate histories or when infants have nonspecific symptoms such as vomiting or fussiness. Missed diagnoses can be catastrophic as AHT can lead to permanent brain damage and even death.

Berger and colleagues at Children's Hospital and the Safar Center for Resuscitation Research at Pitt's School of Medicine have long been researching approaches to detect acute intracranial hemorrhage in infants at risk.

In the current study, the researchers collaborated with Axela, a Canadian molecular diagnostics company, to develop a sensitive test that could reduce the chances of a missed diagnosis by using a combination of three biomarkers along with a measure of the patient's level of hemoglobin, the protein that carries oxygen in blood. Axela's automated

testing system allowed the researchers to measure multiple biomarkers simultaneously using an extremely small amount of blood, an important characteristic of a test designed to be used in infants.

To arrive at the formula, called the Biomarkers for Infant Brain Injury Score (BIBIS), for discriminating between infants with and without intracranial hemorrhage, the team used previously stored serum samples from a databank established at the Safar Center.

The team then evaluated the predictive capacity of the BIBIS value in a second population of 599 infants who were prospectively enrolled at three study sites in the United States. In addition to Children's Hospital, infants were enrolled at Ann and Robert H. Lurie Children's Hospital in Chicago and Primary Children's Hospital in Salt Lake City. The test correctly detected acute intracranial hemorrhage because of abusive head trauma approximately 90 percent of the time, a much higher rate than the sensitivity of [clinical judgement](#), which is approximately 70 percent.

"The test is not intended to replace clinical judgement, which is crucial," said Dr. Berger. "Rather, we believe that it can supplement clinical evaluation and in cases where symptoms may be unclear, help physicians make a decision about whether an infant needs brain imaging."

The specificity of the test—or the ability to correctly identify an infant without bleeding of the brain who would not require further evaluation—was 48 percent. The researchers aimed for the test to be highly sensitive rather than maximizing accuracy, since missing a diagnosis has more serious consequences than performing brain imaging in babies without the condition.

"This study illustrates the benefits of being able to perform highly sensitive tests at the point of care," said Paul Smith, President and CEO

of Axela and a co-author of the study.

Pitt, Dr. Berger and Axela have filed a joint U.S. patent for the test.

Provided by University of Pittsburgh Schools of the Health Sciences

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